

Notice of Allowability

Application No.

10/089,789

Applicant(s)

MIYATA, TOSHIO

Examiner

James H. Alstrum-Acevedo

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's arguments/remarks submitted May 15, 2006.
2. ☒ The allowed claim(s) is/are 32-34 and 36-48.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

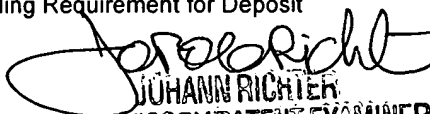
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 5/15/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1617

Reasons For Allowance

The following is an examiner's statement of reasons for allowance: the prior art does not teach or suggest a method of removing glyoxal or methylglyoxal from one or more body fluids comprising contacting a carrier on which one or more biguanide agents have been immobilized with said body fluids, thereby removing glyoxal and methylglyoxal, wherein the biguanide agents are phenformin, buformin, and pharmacologically acceptable salts thereof. The selection of phenformin and buformin as the biguanide agents is not obvious over other biguanide agents, because as demonstrated in Figures 19-21 in U.S. Patent No. 6,919,326 (commonly owned by Applicant) the structural similarity (i.e. presence of at least one guanidine moiety) between aminoguanidine, metformin, and buformin is not predictive of the ability of these compounds to undergo reaction with known active carbonyl compounds (e.g. 3-deoxyglucosone was not trapped by metformin, buformin, and phenformin, but was trapped by aminoguanidine). In addition, studies by Lehnert *et al.* (*Eur. J. Canc.* **1996**, 32A(5), 862-867) (Applicant's Exhibit A, submitted with the arguments/remarks received on May 15, 2006) have demonstrated that the reactivity of drugs in blood serum does not necessarily reflect observed *in vitro* reactivity and that there is little to no predictability regarding which drugs may or not exhibit diminished reactivity when used *in vivo* or in contact with blood serum. For these reasons a person of ordinary skill would not have had reasonable expectation of successfully removing glyoxal and methylglyoxal from body fluids upon contacting said fluid with a carrier comprising immobilized buformin or phenformin. Regarding previously made obviousness-type double patenting rejections, these have all been overcome by Applicant's filing of terminal disclaimers with payment of the appropriate fees.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

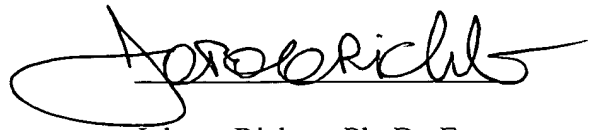
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Patent Examiner
Technology Center 1600

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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning and a horizontal line extending from the end.

Johann Richter, Ph. D., Esq.
Supervisory Patent Examiner
Technology Center 1600